K981394

SEP 28 1998

SECTION 2. SUMMARY & CERTIFICATION

510(k) SUMMARY

- **Submitted By:** Braemar, Inc.
  11481 Rupp Drive
  Burnsville, MN 55337

- **Contact Person:** David Norberg

- **Device:** ER700 Series Cardiac Event Monitor
  Class: IIa

- **Description:** The ER700 Series is a family of patient-activated ambulatory electrocardiograph event recorders.

- **Intended Use:** To record infrequent and elusive ECG heart arrhythmia data. Once an event is recorded, patients transmit the recorded ECG data over the telephone. Or, as an alternative, the ER700 Series allows the ECG data to be transferred directly to a host PC if the patient returns the unit to the clinic.

- **Substantially Equivalent (SE) To:** Braemar ER300 Series
  510(k) # K923930

- **Comparison To The SE Device:**

Attribute	ER700 Series	ER300 Series
Liquid Crystal Display (LCD)	Yes	No
Looping memory	Yes	Yes
Memory type	Flash (non-volatile)	Solid State (volatile)
Number of ECG channels	One or two	One or two
Transtelephonic data transfer	Yes	Yes
Belt clip	Yes	Yes
Direct Data Transfer	Yes	No
Battery	Two AAA	One 9V

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 1998

Mr. David Norberg
Braemar
11481 Rupp Drive
Burnsville, MN 55337

Re: K981394
Braemar ER700 Series AECG Event Recorder
Regulatory Class: II (two)
Product Code: MSH
Dated: August 14, 1998
Received: August 17, 1998

Dear Mr. Norberg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K981394

DEVICE NAME: ER700 SERIES AECG EVENT MONITOR

INDICATIONS FOR USE:

TO RECORD INFREQUENT AND ELUSIVE ECG HEART ARRHYTHMIA DATA. ONCE THE EVENT IS RECORDED, PATIENTS TRANSMIT THE RECORDED ECG DATA OVER THE TELEPHONE. OR, AS AN ALTERNATE, THE ER700 SERIES ALLOWS THE ECG DATA TO BE TRANSFERRED DIRECTLY TO A HOST PC IF THE PATIENT RETURNS THE UNIT TO THE CLINIC.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K981394